IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kistner, et al.

Application No.: 10/006,671

Filed: December 10, 2001

For: ENVELOPED VIRUS VACCINE AND METHOD OF PRODUCTION

Customer No.: 20350

Declaration of Kistner and Reiter

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Otfried Kistner and Manfred Reiter, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of our own knowledge are true and statements made on information or beliefs are believed to be true.

2. I, Otfried Kistner, am currently a Scientist at Baxter BioScience, in Orth/Donau, Austria. I have worked in the field of Virology and Vaccine development for 22 years. I have a Ph.D. degree in virology from the Justus –Liebig University of Giessen. A copy of my *Curriculum Vitae* is attached as Exhibit A. I, Manfred Reiter, am currently a Scientist and Director of Upstream Process Development at Baxter BioScience, in Orth/Donau, Austria. I have worked in the field of process development for 20 years. I have a Ph.D. degree in Biotechnology from the University of Agriculture and Forestry, Vienna . A

copy of my *Curriculum Vitae* is attached as Exhibit B. We are the joint inventors of the above-referenced application, filed on December 10, 2001.

3. We have reviewed the Office Action mailed on October 12, 2005 in connection with the above-referenced application. We understand that the Examiner has rejected claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 as being allegedly obvious over U.S. Patent No. 5,789,245, Dubensky *et al.* (herein "Dubensky"). In particular, we understand that the Examiner asserts that "[H]ad one of ordinary skill performed Dubensky's method with RRV, the virus intermediate would have necessarily been about 97% pure," as achieved in our methods. This declaration is provided to show that, in fact, Dubensky's method cannot produce virus of the purity achieved by our method.

4. We have performed an experiment in the laboratory wherein we carried out Dubensky's method next to our own method in order to obtain RRV intermediate so that we could test and compare its purity. A VERO cell culture was infected with RRV, incubated and propagated in a bioreactor. More specifically, cells of a working cell bank were expanded in T-flasks and roller bottles with a split ratio of 1:6. Propagation of the cells was performed in a stirred tank bioreactor using CYTODEX3 microcarrier as attachment substrate. The cells were grown at 37°C. The culture conditions of oxygen saturation 20% +/- 10% and pH 7.25 +/- 0.35 were kept constant during virus propagation. A serum free VERO cell culture was infected with RRV at a multiplicity of infection of 0.001. After an incubation time of three days (66 hrs) at 37°C the virus was harvested from the bioreactor.

5. First, we followed Dubensky's teachings and passed the harvested virus through a 0.8/0.65 micron filter in order to clarify the crude RRV according to Dubensky's method (see column 120 in U.S. Patent No. 5,789,245). Second, we followed the teachings of the specification and passed the virus harvest (from the same bioreactor), after separation at ~9000g through a 1.2 micron filter and then through a 0.45 micron filter and finally through a 0.22 micron filter in order to clarify the crude RRV according to our own

method (see page 12, paragraph 049 of the specification). We then assessed the purity of each virus intermediate through Vero-DNA, protein and TCID50 analysis

6. The results showed that the RRV intermediate obtained with our method has a DNA content of 11.8 ng (0.45μ filter) and 11.9 ng (0.22m filter) per 10^7 TCID50 while the RRV intermediate obtained with Dubensky's method has a DNA content of 95.7 ng DNA per 10^7 TCID50. In addition, we have compared the purity of the virus intermediates (obtained with each method) on a DNA to total protein basis and established that Dubensky's method would only lead to an intermediate virus product of 1.62ng DNA per μg protein. In comparison, our method leads to substantially higher purity of the intermediate with a DNA content of 0.23 ng per μg of protein (1.2/45μ filtration) and a DNA content of 0.08 ng per μg protein for the 1.2/0.45μ/0.22μ filtration. Both size exclusions, 0,2 and 0.45 were chosen according to the published pore size range of 0.1-0.5 micron. In addition, we have filtered the 0.8/0.65 micron filtrate (intermediate according to Dubensky's method) with a 0.22micron filter. With this additional filtration step according to our method a significant decrease in DNA content to 63.4 ng/10^7 TCID50and an improved DNA/protein ratio 0.73ng per μg of protein could be achieved. For all experiments identical starting material with a TCID50 of 4.91 x 10^7 was used. The results are summarized in the tables below:

THE CLAIMED METHOD		
	DNA/Virus Titer [ngDNA/10^7($TCID_{50}$/ml)]	DNA/Protein [ngDNA/μgProtein]
Filtration: 1.2 μm/0.45 μm	11.8	0.23
Filtration: 1.2 μm/0.45/0.2 μm	11.9	0.08

DUBENSKY'S METHOD		
	DNA/Virus Titer [ngDNA/10^7($TCID_{50}$/ml)]	DNA/Protein [ngDNA/μgProtein]
Filtration: 0.8 μm/0.65 μm	95.7	1.62
Filtration: 0.8 μm/0.65 μm/0.2μm	63.4	0.73

Date Otfried Kistner, Ph.D.

Date Manfred Reiter, Ph.D.

Baxter
BioScience

Curriculum Vitae

Name	Manfred Reiter
Degrees	Dipl. Ing., Dr. rer. nat.
Position	Director Upstream Process Development Baxter BioScience
Location	Biomedical Research Center Orth/Donau

Education

1966 – 1970	Primary School
1970 – 1978	High School
1978 – 1986	University Agriculture and Forestry, Vienna, Austria
1986	Diplom Ingenieur (eq. Masters Degree)
1989	PhD

How long at Baxter BioScience	12 years

Job experience

1983 – 1986	Fermentation technology
1986 – 1989	Cell culture technology (Vero, CHO, Hybridoma)
1991 – 1993	Lecturer for animal cell biotechnology at Institute Applied Microbiology
1993	Immuno AG, Biomedical Research Center, Orth, Austria
1998	Manager Microbiological and Cellbiological Process Development
2000	Director Upstream Process Development Baxter BioScience

Fields of expertise	Biotechnology, Microbiology, Cell Culture, Screening, Fermentation Technology Recombinants and Vaccines, Separation, Filtration, Ultracentrifugation, Virus Inactivation, GMP Cell Banking, Clinical Manufacturing, Scale-up

M. Reiter 17.03.2006

M. Reiter

PUBLICATIONS / PATENTS / AWARDS

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M. Reiter 17.03.2006

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M. Reiter 17.03.2006

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M. Reiter 17.03.2006

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Meyer H, Reiter M, Mundt W, Barrett N and Dorner F (2005) Method for large scale production of Hepatitis A virus. US 6,855,535.

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Reiter M, Mundt W, Dorner F, Grillberger L and Mitterer A (2003) Medium for the protein-free and serum-free cultivation of cells. Patent application US 2003/0203448A1.

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Kistner O, Reiter M, Bruehmann A, Barrett N, Mundt W and Dorner F (2003) Enveloped virus vaccine and method for production. Patent application US 2003/0108859A1.

M. Reiter 17.03.2006

Baxter Technical Awards

Science and Technology Award 1997, Baxter International Inc.
The next Generation of Recombinate™

Outstanding Science and Technology Award 1998, Baxter International Inc.
Vero Cell Derived Vaccines

Special Accomplishment Award 1999, Baxter International Inc.
Novel Vero Cell Derived Influenza Vaccine

Special Accomplishment Award 1999, Baxter International Inc.
Development of a Ross River Candidate Vaccine

Special Accomplishment Award 1999, Baxter International Inc.
Preclinical Development of a Hepatitis A Virus Vaccine

Outstanding Science and Technology Award 1999, Baxter International Inc.
Protein-free Culture Medium for Therapeutics and Vaccines

Special Accomplishment Award 2000, Baxter International Inc.
Guaranteed TSE-free Trypsin for Biotechnological Processes

Customer First Award 2001, Baxter International Inc.
Development and Delivery of a Candidate Smallpox Vaccine

Distinguished Scientist Award 2002, Baxter International Inc.
Production of 500 Million Dose Equivalent of Smallpox Vaccine

M. Reiter 17.03.2006

Curriculum Vitae

Name:	Otfried Kistner
Degrees:	Ph.D.
Position:	Senior Director Virology
Location:	Baxter BioScience, Biomedical Research Center, Orth/Donau, Austria

Education:

1978-1984	Justus-Liebig-University, Giessen, Germany Diploma in Biology
1984-1987	Justus-Liebig-University, Giessen, Germany Ph.D. in Virology

Other training: Cell Biology, Immunology, Biochemistry, Statistics

Employment History:

1982 - 1984	Trainee, Institute of Virology, University of Giessen, Germany
1984 - 1987	Research Fellow, Institute of Virology, University of Giessen, Germany
1987 - 1988	Research Assistant, Institute of Virology, University of Giessen, Germany
1988 - 1990	Research Scientist Virology, Immuno AG, Austria
1991 - 1996	Head of Laboratory Virology, Immuno AG, Austria
1997 - 1998	Head of Department Experimental Virology, Baxter Hyland Immuno, Austria
1998 - 1999	Head of Departments Experimental Virology and Viral Vaccines, Baxter Hyland Immuno, Austria
2000 - 2004	Director Virology (responsible for departments "Experimental Virology", "Viral Vaccines" and "Preclinical Research"), Baxter BioScience, Austria
since 2004	Senior Director Virology / Viral Vaccines, Baxter BioScience, Austria

Fields of Expertise: Vaccine Development (R & D , Preclinic, Clinic in part) Establishment of new Methodologies, Quality Control, Regulatory Affairs, Biological Safety

Number of publications: 19 Publications, 9 Patents

Publications:

1. O. Kistner, H. Müller, H. Becht and C. Scholtissek (1985)
Phosphopeptide Fingerprints of Nucleoproteins of Various Influenza A Strains Grown in Different Host Cells.
J. Gen. Virol. **66**, 465-472

2. C. Scholtissek, H. Bürger, O. Kistner and K. F. Shortridge (1985)
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Virology **147**, 285-294

3. C. Scholtissek, H. Bürger, O. Kistner and K. F. Shortridge (1987)
The Nucleoprotein (NP) as a Possible Major Factor in Determining Host Specifity of Influenza H3N2 Viruses of Southern China.
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4. O. Kistner, K. Müller and C. Scholtissek (1989)
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Thromb. Haemost. **68**, 119-124

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9. O. Kistner, P. N. Barrett, W. Mundt, M. Reiter, S. Schober-Bendixen and F. Dorner (1998)
Development of a Mammalian Cell (VERO)-Derived Candidate Influenza Virus Vaccine.
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10. O. Kistner, P. N. Barrett, W. Mundt, M. Reiter, S. Schober-Bendixen, G. Eder and F. Dorner (1999)
Development of a Vero Cell-Derived Influenza Whole Virus Vaccine.
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11. O. Kistner, P. N. Barrett, W. Mundt, M. Reiter, S. Schober-Bendixen, G. Eder and F. Dorner (1999)
A Novel Mammalian Cell (Vero) Derived Influenza Virus Vaccine: Development, Characterization and Industrial Scale Production
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12. P. Brühl, A. Kerschbaum, O. Kistner, N. Barrett, F. Dorner and M. Gerencer (2001)
Humoral and Cell-Mediated Immunity to Vero Cell-Derived Influenza Vaccine.
Vaccine **19**, 1149-1158

13. O. Kistner, P. N. Barrett, W. Mundt, M. Reiter, S. Schober-Bendixen, G. Eder and F. Dorner (2001)
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14. I. Jabbal-Gil, W. Lin, O. Kistner, S. S. Davis, and L. Illum (2001)
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1. Method for producing biologicals in protein-free culture
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2. Production of orthomyxoviruses in monkey kidney cells using protein-free media
   Patents No:
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3. Method for producing influenza virus and vaccine
   Patent No:
   US 5.698.433

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   Patent No:
   US 5.753.489

5. Method for controlling the infectivity of viruses
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6. Method of inactivating lipid-enveloped viruses
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7. Novel Influenza virus vaccine composition
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8. Inactivated influenza virus vaccine for nasal or oral adminstration
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9. Enveloped virus vaccine and method for production
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